Guidance on Temporary Variances for Research Studies
NOSB Crops and Policy Development Committees
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Introduction:

A core principle of organic agriculture is the adoption of best sustainable and ecologically sound practices and inputs as they become available. Organic agricultural research is used to assess and develop emerging practices and inputs. It is a dynamic field with new information available regularly. Organic producers, handlers, and consumers all receive benefits from research on new methods, practices, varieties, and breeds.

In recent years, federal, state, university, and private funds have become available for organic agricultural research. Some of the grant funds require that research be conducted on transitional or certified organic land. For example, the Integrated Organic Program of USDA currently requires that all research be done on land that is either certified or transitioning to organic, thus the ability of researchers to get their research lands certified has a direct bearing on their eligibility for funding.

The validity of the research to organic growers is an important concern. However, many organic growers do not find research conducted on non-certified land to be applicable in organic systems. The USDA Integrated Organic Program relies heavily on stakeholder input and information transfer to organic growers. Therefore, the benefits of using cutting-edge research methods must be balanced by the potential loss of applicability to the ultimate end-users of the research.

National Organic Program rule section 205.290(a)(3) allows the Administrator of USDA's Agricultural Marketing Service (AMS) to establish temporary variances from certain regulatory provisions for conducting research. The regulation does not define "research" or require that research follow scientific methods or be conducted only by universities or research institutes.

Researchers, farmers, and certifying agents are aware that the regulation allows for research variances, but confusion exists as to the types of variances that are allowed. In order to bring consistency and clarity, the NOSB recommends that the USDA issue guidance concerning temporary variances allowed for research purposes. Guidance on research variances should balance the need for research flexibility with the relevance of the research to organic growers and consumers.

Background:

Regulatory citation

NOP rule section 205.290 states the following:
"(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:
(3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

(e) Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105."

According to §205.290(a), the following sections are eligible for consideration for temporary variances:
§205.203 Soil fertility and crop nutrient management practice standard.
§205.204 Seeds and planting stock practice standard.
§205.205 Crop rotation practice standard.
§205.206 Crop pest, weed, and disease management practice standard.
§205.207 Wild-crop harvesting practice standard.
§205.236 Origin of livestock.
§205.237 Livestock feed.
§205.238 Livestock health care practice standard.
§205.239 Livestock living conditions.
§205.270 Organic handling requirements.
§205.271 Facility pest management practice standard.
§205.272 Commingling and contact with prohibited substance prevention practice standard.

Discussion

Since no other section numbers are listed in §205.290(a), other sections of the regulation, such as those pertaining to recordkeeping (§205.103), allowed and prohibited substances (§205.105 and §205.600-607), organic system plans (§205.201), land requirements (§205.200 and §205.202), labeling (Subpart D), certification (Subpart E), and administrative requirements (Subpart F), are not eligible for consideration.

While the regulation does not define "research", it is imperative that approved research projects must: 1) follow the scientific method; 2) be designed to provide data and knowledge that are valid in the context of organic production and handling systems; and 3) be conducted to protect the organic integrity and validity of the site used for organic research.

Recommendation:

To bring consistency and clarity concerning temporary variances allowed for research purposes, the NOSB recommends the USDA issue the following guidance:

A. For research sites where products <u>may not</u> enter organic commerce

1) A valid research plan with projected benefits and scientific method must be submitted to the certification agent.
2) Products may be produced under research variances to the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272, provided that the operation is certified and the operation complies with all other regulatory requirements.
3) Land to which prohibited substances have been applied under a research variance is not eligible to produce crops or products to be sold as organic until the land requirements in §205.202 and all other applicable regulatory provisions are fulfilled.
4) Buffer zone requirements may be waived.

B. For research projects on certified operations where products may enter organic commerce
   1) A valid research plan with projected benefits and scientific method must be submitted to the certification agent.
   2) Products may be produced under research variances to the requirements in §§ 205.203 through 205.207 and 205.270 through 205.272, provided that the operation is certified and the operation complies with all other regulatory requirements.

C. The Administrator may authorize accredited certifying agents to issue research variances when reviewing and approving a research project's Organic System Plan and research plan.

D. To be considered for a research variance, an application should be submitted to an accredited certifying agent that includes, in addition to the Organic System Plan, the following information:
   1) A research plan with projected benefits and a description of the scientific method to be followed;
   2) A listing of the otherwise-prohibited practices or substances for which the variance is sought;
   3) A citation of the sections of the NOP rule for which the variance is sought;
   4) The specific location (field number, plot plan, etc.) where such practices or substances would be applied;
   5) The timeframe for which the variance is sought and for which the practices or substances will be used;
   6) A brief justification of why the practices or substances are needed and whether approved alternatives are available;
   7) A description of how non-certified products will be separated from certified organic products to prevent contamination or commingling, if applicable; and
   8) A description of how the land will be managed to regain full certification after the variance has expired.

E. Accredited certifying agents should be required to annually submit to the Administrator a list of all research variances granted, itemizing the exact variances granted (including rule citations), justification for the variance(s), and the names of all operations to whom research variances have been granted.

F. Organic Certificates issued for research sites must state whether crops/products may be marketed as organic.

Questions and Answers:

The NOSB has received input containing examples of the types of issues of concern to researchers. Each of the issues needs to be evaluated in light of the concerns by the organic community that research be conducted within the overall context of an organic system. Researchers have submitted the following concerns/questions and the NOSB has provided the recommended responses/answers:

Question 1) Some scientists evaluating pest controls and yield losses feel it would be desirable to include a comparison treatment with prohibited materials in order to assess potential yields of organic crops vs crops produced using nonorganic methods. While

these scientists agree that products from such studies could not be marketed as organic, they would like to relax rules regarding buffer zones or the requirement for an additional three-year transition after such applications.

Answer 1) The research site could be certified organic, however crops or products treated with prohibited pesticides or other prohibited substances could not be marketed as organic. Buffer zones needed to produce crops or products to be sold as organic would not need to be maintained, if the crops or products are not to be sold as organic. Land to which prohibited substances were applied would need to be free of prohibited substances for 36 months prior to harvest of crops or products to be sold as organic.

[Note – The NOSB recognizes that in response to grower demand for comparison studies, some researchers would like to conduct studies on certified organic land in order that organic practices receive a fair comparison with conventional practices. We do not believe that this is an adequate reason to grant variances for routine pesticide applications on certified organic land. It is important that the scientific community continue to expand its awareness of what comprises a “fair” trial of organic practices. Organic farmers do not need comparative studies that assess the performance of organic practices with conventional practices as much as they need studies that elucidate optimal production practices and inputs under certified organic conditions.]

Question 2) Scientists studying nutrient cycling in soils often use radio-isotopes (e.g., P-35) as tracers. The radio-isotope would clearly be a prohibited material, but the half-life for these isotopes is well known and in many cases, they will disintegrate to background levels in one season.

Answer 2) The research site could be certified organic. Products from studies using radio-isotopes or other prohibited substances could not be marketed as organic. Buffer zones would not need to be maintained. Land to which radio-isotopes or other prohibited substances were applied would need to be free of prohibited substances for 36 months prior to harvest of crops or products to be sold as organic.

Question 3) Buffer zone requirements consume large amounts of land when replicated comparisons of conventional and organic treatments are done in a randomized field experiment. Relaxation from the buffer zone rules would increase research efficiency and reduce the cost of such experiments.

Answer 3) The research site could be certified organic. If substances or practices prohibited in 205.105 are used, the crops cannot be sold as organic. Buffer zones would not need to be maintained, if the crops or products are not to be sold as organic. If the products are to be sold as organic, then buffer zones must be maintained per §205.202(c).

[Note – While the regulation allows reductions in buffer zone requirements under a research variance, researchers should take steps to prevent chemical and/or genetic drift from occurring in order to protect the validity of the research.]

Question 4) Trials of experimental materials to aid organic production, including but not limited to those for pest and disease control, weed control, soil fertility and crop nutrition, and post-harvest handling and storage, that are still under development often involve products not yet approved or even submitted for review by the NOSB. In some cases,

such substances may contain inert ingredients not yet approved. Many companies developing commercial products are hesitant to invest in the necessary development costs until a product has proven efficacy over more than a limited range of sites. This creates a “Catch-22” that slows the commercial development of production and handling inputs and delays their availability for organic producers. Variances for research purposes would speed commercialization of such products and aid organic producers.

Answer 4) The research site could be certified organic, but no crop may enter organic commerce when prohibited (non-approved synthetic or prohibited nonsynthetic substances) are used. Products produced using experimental nonsynthetic substances can be marketed as organic, provided there is legal authority under FIFRA or other applicable statutes for use of the substance as applied, unless the substances are listed on §205.602 or §205.604. Products produced using experimental synthetic substances not on the National List cannot be sold as organic. Land to which non-approved (prohibited) substances were applied would need to be free of prohibited substances for 36 months prior to harvest of crops or products to be sold as organic.

Question 5) Certain experimental monitoring processes, although considered state-of-the-art from a scientific standpoint, may not be allowed under current NOP rules, e.g., neutron probe for soil moisture measurements, chemicals used for extractions in soil, genetically-marked microorganisms, etc. In some cases these are considered standard methods, and failure to use them makes it more difficult to publish research results in peer-reviewed scientific journals. Variances to authorize such methods could be helpful in attracting state-of-the-art science to organic research.

Answer 5) The research site could be certified organic. Monitoring technology that does not introduce a synthetic substance into the crop environment, such as neutron probes, is not a factor, and no research variance is needed. Products produced using experimental nonsynthetic substances can be marketed as organic, unless the substances are listed on §205.602 or §205.604. Products produced using experimental synthetic substances not on the National List or excluded methods, irradiation, or sewage sludge cannot be sold as organic. Land to which non-approved (prohibited) substances were applied would need to be free of prohibited substances for 36 months prior to harvest of crops or products to be sold as organic.

Question 6) A researcher conducts vegetable variety trials. It is often not possible to get untreated seed of new varieties or breeding lines, making it impossible to integrate the treated seed varieties/lines into the organic plots. Instead, the treated seeds are planted in a separate but adjacent block. This prohibits the researcher from analyzing the data as one data set and directly comparing variety performance in the studies. The researcher would like to have a temporary variance that would allow treated seeds to be planted in the variety trials. In addition, seed companies need efficacy data of their varieties in organic systems before they are willing to make untreated (let alone organic) seeds available. A similar situation exists for organic seed breeding programs, where foundation seeds may only be available as treated with prohibited substances.

Answer 6) The research site could be certified organic, but no seeds or crops produced using seeds treated with prohibited substances may be sold as organic. Land where treated seeds were planted would need to be free of prohibited substances for 36 months prior to harvest of crops or products to be sold as organic.

Question 7) Organic livestock health standards mandate that sick animals that do not respond to organic methods must be treated with synthetic medications to protect the health and well-being of the animals. While this standard is an essential animal welfare requirement, it is sometimes a constraint in research evaluating animal health treatments. For crop plants, an untreated control can simply be plowed under, but no ethical option exists for untreated controls in animal veterinary research. Any livestock research funded by USDA must pass animal welfare committee reviews. While these may have less stringent requirements than the NOP rule, they are designed to prevent research abuses of animals in experiments. Some researchers would like their animal welfare review committee approval of experimental protocols to be deemed adequate for organic certification purposes.

Answer 7) Since organic livestock must be treated humanely, there is no need for a variance on §205.238. If a synthetic substance is used for livestock health care that is not on the National List, the animal or its products cannot be sold as organic, per §205.238(c)(7).

Committee vote:
To be determined